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Original Filing Date: July 27, 2012
Redacted Filing Date: August 3, 2012

REDACTED -- PUBLIC VERSION

BY E-FILING AND FAX

The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 09-037-RBK-JS

Dear Judge Schneider:

Plaintiff Shionogi Pharma, Inc. ("Shionogi") submits this letter in response to Defendant Mylan's letter of July 20, 2012, D.I. 505, regarding the discoverability of [redacted].

A. [redacted] is not a "Settlement Agreement"

[redacted]

[redacted] Understood in this light, Mylan's repeated reliance on Federal Rule of Evidence 408 is simply inapposite. FRE 408 does not apply here.

B. [redacted] Is Discoverable

Even assuming *arguendo* that the [redacted] could properly be characterized as a "settlement agreement" within the meaning of FRE 408, that agreement and the underlying negotiations and forecasts are still discoverable under governing Federal Circuit authority. Specifically, the Federal Circuit has made clear that "settlement negotiations related to reasonable royalties and damages calculations are not protected by a settlement negotiation privilege." *In re MSTG, Inc.*, 675 F.3d 1337 (Fed. Cir. 2012). In *MSTG*, the Court also noted that "[o]ur cases appropriately recognize that settlement agreements can be pertinent to the issue of reasonable royalties." *Id.* at 1348 (citing *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869-873 (Fed. Cir. 2010)). Thus, there is no general bar to discovery here and the Federal Circuit's decisions in *MSTG* and in *ResQNet.com* should end the inquiry.

As one district court stated in dealing with a similar discovery dispute:

> Simply put, the Federal Circuit's ruling in *ResQNet.com* forecloses VMI's categorical contention that "[a]greements reached to resolve patent litigation are not relevant to the calculation of a reasonable royalty." The vast majority of courts to consider the relevance of settlement agreements (and offers) to the subject of patent damages in light of *ResQNet.com* have reached the same conclusion about said decision's meaning and import.

Volumetrics Med. Imaging, LLC v. Toshiba America Med. Sys., Inc., 2011 WL 2470460, at *14 (M.D.N.C. June 20, 2011) (and cases cited therein); *see also Caluori v. One World Techs., Inc.*, 2012 WL 630246, at *4 (C.D. Cal. Feb. 27, 2012) ("[N]umerous district court holdings since *ResQNet* confirm that it is not unreasonable to rely on a settlement agreement for the purpose of

[1] Indeed, Lupin's expert Mr. Hofmann asserted to the Court that, as to [redacted] discussions concerning the sale of an ANDA are "not a negotiation for the patents-in-suit because the ANDA filer has no rights to the patent-in-suit." D.I. 436 (Mar. 7, 2012 Hofmann Decl.) at ¶ 32. Similarly, Lupin asserted to the Court that "[t]he purchaser of an ANDA would not receive a license to sell a product protected by a patent assumed valid and infringed." D.I. 435 (Lupin's Protective Order Reply Brief) at 10. These statements directly contradict Mylan's assertion that the disputed transaction was part of "global settlement negotiations."

establishing reasonable royalty rates."). Accordingly, there can be no dispute that "settlement agreements" are discoverable, and indeed, can be some of the most probative evidence as to a reasonable royalty in the context of patent damages. *See ResQNet*, 594 F.3d at 869-73.

1. [redacted] Relevant to Damages and to Secondary Considerations of Non-obviousness

Although [redacted] and Lupin have deprived Shionogi of the discovery, Shionogi believes that the [redacted] as well internal analyses and communications between those parties, are relevant at least to damages and to secondary considerations of non-obviousness.

The value that [redacted] placed on Lupin's infringing ANDA and product, the price paid for the ANDA, and any royalties to be paid by [redacted] to Lupin, would at a minimum be relevant evidence to the issue of reasonable royalty damages. *See, e.g.*, *In re MSTG*, 675 F.3d at 1348; *ResQNet*, 594 F.3d at 869-73; *Micro Chemical, Inc. v. Lextron, Inc*., 317 F. 3d 1387, 1393 (Fed. Cir. 2003).

[redacted] is also likely relevant to secondary considerations of non-obviousness, such as the commercial success of the patented invention and copying of the invention by others. Both Lupin and Mylan assert that the two patents-in-suit are invalid as obvious. The law requires considerations of evidence of these secondary considerations of non-obviousness. Here, the claimed invention is embodied by the infringing Lupin product and ANDA, and evidence regarding the purchase of that infringing ANDA and product [redacted] would go directly to show the commercial success of the claimed invention. *See Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contrs. USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010) (licensing agreement was relevant to commercial success even though negotiated under threat of litigation).

2. Whether the [redacted] Will Be Admissible At Trial Does Not Determine Whether It is Discoverable Now

Mylan argues that because the [redacted] is not admissible as a "settlement negotiation," it likewise is not discoverable. Shionogi disagrees. For the reasons explained above, the [redacted] does not constitute a "settlement negotiation," and is admissible and relevant.

In any event, Mylan's argument is legally flawed, because discovery is not limited to admissible evidence. Rule 26 expressly states that "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." FED. R. CIV. P. 26(a)(1). Indeed, Lupin has already conceded that the [redacted]

[redacted] is discoverable by agreeing to produce it, along with associated documents.[2] D.I. 487, Ex. I (email from Lupin to Shionogi, dated June 27, 2012).

Whether [redacted] is admissible depends on both the contents of that [redacted] as well as the purposes for which it might be put into evidence. As this Court has acknowledged, admissibility is an issue to be determined at trial. May 11 Hearing Tr. at 78:18-20; *see also In re MSTG*, 675 F.3d at 1345 ("Rule 408 itself contemplates a host of scenarios under which documents related to settlement negotiations would be admissible for purposes other than [those excluded by FRE 408]."). Of course, neither the Court nor Shionogi have the benefit of knowing the contents of the [redacted] itself, or of documents related to the negotiation. Yet, Mylan seeks to rely on admissibility as both a sword and a shield, when Defendants alone have possession of those documents. That is unfair in the extreme.[3]

But in any event, as discussed above, [redacted] is reasonably calculated to lead to admissible evidence about the value that Lupin placed on the patented product, among other issues, and secondary considerations of non-obviousness. Indeed, it could potentially be the most probative evidence given that it directly involves the technology in suit. Whether or not [redacted] will ultimately prove admissible at trial is an issue for another day, and in any event, does not determine its discoverability.

C. Mylan's Attempts To Distinguish *In re MSTG* Are Unavailing

Mylan also asserts that *In re MSTG* does not disturb the cases it cites in its July 5, 2012 pre-conference letter in which courts have excluded settlement agreements and negotiations. *See* D.I. 505 at 4-8. Shionogi disagrees. Clearly, the Federal Circuit's ruling is controlling. Even if it were not, Mylan's cases are irrelevant to the discoverability of [redacted] Those cases all pre-date *In re MSTG*, and all but two pre-date *ResQNet*. Moreover, those cases concern admissibility at trial, and thus should not be determinative of a discovery

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[2] That Lupin later rescinded that agreement after Mylan objected does not alter Lupin's prior concession.

[3] The dispute between Shionogi and Mylan is also in a similar posture to the dispute between MSTG and AT&T in *In re MSTG*. Here, Mylan argues by fiat that the requested documents will not contain the relevant information, but refuses to produce the documents such that Shionogi can test that assertion. Indeed, co-defendant Lupin has submitted expert testimony declaring that [redacted] "reflect" certain "belief[s]" of Lupin and Mylan, and that the "first-to-file status [associated with Lupin's ANDA] represents additional value to the potential generic buyer of the ANDA . . . ." *See* D.I. 436 (Hofmann Decl.) at ¶ 31. Shionogi is entitled to explore these statements, and the facts upon which they are based. The Federal Circuit's holding in *MSTG* that "[a]s a matter of fairness MSTG cannot at one and the same time have its expert rely on information about the settlement negotiations and deny discovery as to those negotiations" is equally applicable here. 675 F.3d at 1348.

dispute,[4] or represent compromise offers between adverse parties in a litigation (again, Mylan and Lupin were not litigation adversaries),[5] or both.

The Federal Circuit in *In re MSTG* has rejected the same policy arguments Mylan makes concerning FRE 408 and this Court need not consider them. Indeed, beyond baldly asserting that production "would chill potential settlement negotiations in this case," D.I. 505 at 1, Mylan offers no proof that "that denial of discovery of the settlement negotiation documents [is] ***necessary*** here to encourage settlement." *In re MSTG*, 675 F.3d at 1348 (emphasis added).[6]

Shionogi therefore respectfully requests that the Court order both Lupin and Mylan to immediately produce all documents responsive to Shionogi's document requests concerning [redacted]

Respectfully submitted,

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)

cc: All Counsel of Record
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4 Mylan cites the following cases that all concern admissibility, not discoverability: *Abbott Labs. v. Sandoz, Inc.*, 743 F. Supp. 2d 762 (N.D. Ill. 2010); *Pioneer Hi-Bred Intern., Inc. v. Ottawa Plant Food, Inc.*, 219 F.R.D. 135 (N.D. Iowa 2003); *Spreadsheet Automation Corp. v. Microsoft Corp.*, 587 F. Supp. 2d 794, 800-01 (E.D. Tex. 2007); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F. Supp. 2d 147, 159 (D.R.I. 2009); *Donnelly Corp. v. Gentex Corp.*, 918 F. Supp. 1126, 1133 (W.D. Mich. 1996).

5 Mylan cites the following cases that concern settlement negotiations between adverse parties, not co-defendants: *Bascom Global Internet Servs. v. AOL LLC*, Civil Action No. 08-1765, 2011 U.S. Dist. LEXIS 100609, at *4 (E.D.N.Y. Sept. 8, 2011); *Vardon Golf Co., Inc. v. BBMG Golf Ltd.*, 156 F.R.D. 641, 652 (N.D. Ill. 1994).

6 [redacted] will contain reliable information relevant to the reasonable royalty calculation, such as the value Lupin placed on its ANDA (and therefore its infringing product). Lupin had no reason to charge [redacted] less than fair value for Lupin's ANDA to reduce costs and end litigation, as there was no litigation between them.